

16. IVI-NICED Collaborative Project

Randomised controlled evaluation of protection by Vi polysaccharide vaccine against typhoid fever in Eastern Kolkata

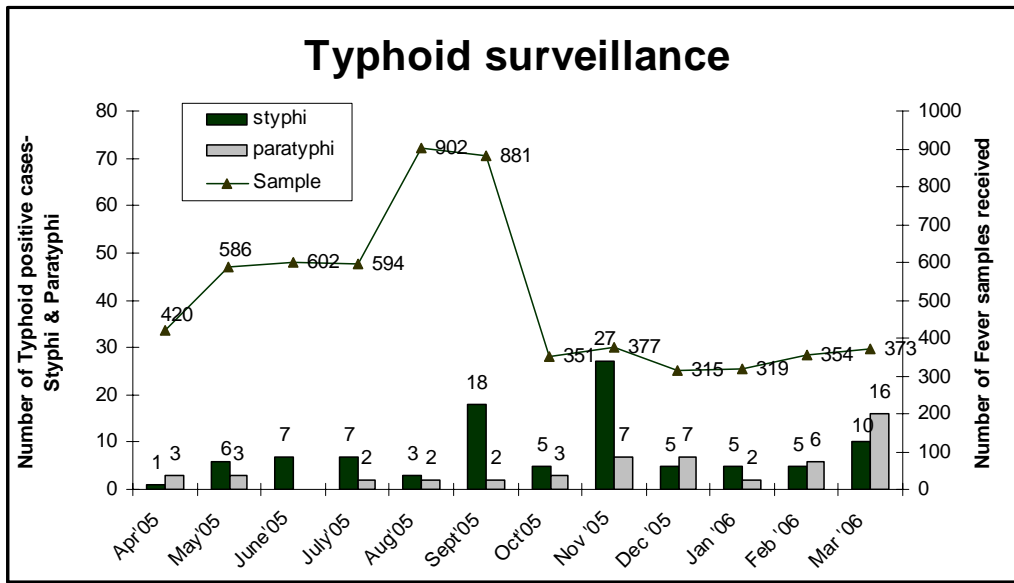
Objectives of the study:

1. to assess safety and feasibility of the vaccine
2. to assess the acceptability of the vaccine by the community
3. to assess efficacy of the vaccine against typhoid fever

Major progress:

We have selected the ward no.29 and 30 of Kolkata Municipal Corporation as study sites. In census survey, we have covered 10,995 families of total 57,099 slum populations. The average family members were 6 and 5 in the ward 29 and ward 30 respectively. After census, the data has been entered into the computer and data has been checked and edited for any duplication / sequence break in family number. The Identification card for each family including all family members in laminated form has been issued to each family. The geographical information system (GIS) of those areas for mapping the disease distribution has been completed. We have set up 5-health outposts, each covering about 12,000 populations for passive surveillance of Cholera and typhoid fever. Another 2 health outposts have been setup in the reference hospitals (Infectious Disease Hospital and B.C. Roy Children Hospital) for surveillance so that the case will not be missed from the study sites. Surveillance for Cholera and typhoid fever has been started from 21st April 2003. From April 2005 to 31st March 2006, 41 cholera was confirmed out of 5603 samples processed of which 35 (0.6%) were Inaba and 6 (0.1%) were Ogawa serotypes. For typhoid fever number positive were 99 (1.6%), for Paratyphi-A 53 (0.8%) out of 6075 samples and Widal test was positive for 1346 (22.2%) samples.

The mass typhoid Vi vaccination campaign was held in the study site from November 27 to December 31, 2004. Out of 60,615 individuals, 54,674 were considered eligible. During the vaccination, those who were considered not eligible were pregnant or lactating women, children < 2 years of age, those with a febrile illness or those travelling out of the study site. 37,686 individuals or 68.9% of 54,674 were immunized. Surveillance for typhoid fever is continuing. The study is in progress.



Socio-behavioral and economic studies on typhoid fever and cholera

Objectives of the study:

1. To estimate the economic costs of cholera and typhoid fever in the community
2. To assess the cost effectiveness of vaccination (e.g., the cost per illness episode avoided, cost per life saved)
3. To evaluate the willingness to pay (private demand) for cholera and typhoid fever in the community

Major progress:

We have started a willingness to pay (WTP) approach to measuring the economic benefits of the vaccines for three reasons. First, WTP is the most comprehensive measure of the private benefits of disease prevention and encompasses at least two additional components of the economic benefits of disease prevention: (1) the avoided intangible costs of disease, like pain and suffering; and (2) the household's value of avoided risk. Second, the comprehensiveness of WTP is likely to be important for the diseases because of their reputation or susceptible populations. For instance, the dread associated with cholera and typhoid fever due to mortality would be reflected in larger WTP estimates. Third, since these vaccines have not been introduced in many countries, there is no evidence of the uptake and benefits that policymakers may expect by their adoption.

Private costs of illness (COI) measures the ex-post costs associated with an episode of illness, including both out-of-pocket expenditures and indirect costs (e.g., lost wages, costs of waiting time). Private cost of illness data is being collected using structured instruments from subjects with laboratory confirmed cholera and typhoid fever. Respondents with cholera are being interviewed two times over a period of two weeks, while those with typhoid fever are being interviewed three times over a period of three months. The study covers duration of illness since the first symptom realized by patient including all sequence symptoms

(sequelae) until cured. The costs include out-of-pocket expenditure such as cost of diagnosis, laboratory tests, medicines and indirect costs in terms of real income loss of patient or family members due to work absence (payment cut and/or cost of substitute labor). Institutional cost data is also being collected and includes recurrent and capital expenditures.

During cholera and typhoid fever (Vi) vaccination trials, two kinds of costs are to be collected. This will include private cost of vaccination defined as expenditure incurred to receive a vaccine and vaccine delivery cost defined as the cost for providing and administering the vaccines. The private costs will be collected from a sample of individuals who receive the vaccines using a structured survey instrument. Vaccine delivery cost including: personnel, equipment and supplies will be calculated based on actual expenditure. Pre-cholera vaccine data collection is going on.

The study is in progress

A randomized controlled trial of the bivalent killed whole cell oral cholera vaccine in Eastern Kolkata, West Bengal, India

Objectives:

Primary objective: To estimate the efficacy of a two-dose primary regimen of the oral killed bivalent cholera vaccine when administered to residents at least 1 year of age of eastern Kolkata, West Bengal, India, in preventing culture-proven *V. cholerae* O1 diarrhoea episodes severe enough to require treatment in a health care facility.

Secondary objectives:

- a. To estimate the efficacy of the vaccine in preventing:
 - Culture-proven *V. cholerae* O1 diarrhoea episodes associated with severe dehydration;
 - Episodes of acute watery diarrhoea associated with severe dehydration;
 - Episodes of acute watery diarrhoea severe enough to require treatment in a health care facility; and
 - All the above endpoints stratified by age (less than 5 and over 5 years)

Major progress:

The extended area of ward 29 and ward no. 33 have been also included for the study area for vaccine trial to reach the sample size of 110,000 population. The census-1 of new area and the census-3 of the existing area have been completed. The GIS work of the new area has been completed. Premises based randomization is complete and vaccination programme will be started from 6th July, 2006

